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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

Enforcement Committee Report

Randy Kajioka, PharmD, Chair
Greg Lippe, Public Board Member
Neil Badlani, Pharmacist Member
Tappan Zee, Public Board Member

There was no meeting of the Enforcement Committee this quarter.

a. FOR DISCUSSION AND POSSIBLE ACTION: Compliance Monitoring for California Patient-Centered Requirements for Prescription Drug Containers as Authorized by Section 4076.5 of the California Business and Professions Code

Attachment 1

The Board of Pharmacy approved the final version of its patient-centered regulation in June 2010. While the regulation was undergoing review by the Administration and approval by the Office of Administrative Law, the board announced the board's finalization of the regulation's provisions in its newsletter and via several subscriber alerts.

The regulation (16 California Code of Regulations section 1707.5) was approved by the required agencies and took effect on January 1, 2011 (as required by Business and Professions Code section 4076.5). The board again notified licensees of its requirements in a newsletter and subscriber alerts.

The text of this regulation is provided as **Attachment 1**.

As of October 2011, the board's inspectors are doing educational compliance to ensure the patient-centered labels will become available where they are not already in use. Where the new labels are not in use, inspectors are encouraging compliance and identifying when compliance has been achieved. We do not yet have full compliance.

For the discussion scheduled at this meeting, the board will discuss when the board should begin stronger compliance of this regulation – using its compliance criteria and sanctions to secure full implementation for all patients in California as required by statute.

b. FOR POSSIBLE ACTION: Board-Sponsored CE Scheduled for November 7 at Loma Linda University School of Pharmacy – A Joint Presentation with the DEA

Attachment 2

On November 7, 2011, board staff will join with the DEA to host a day-long conference on pharmacy issues at Loma Linda University. A similar presentation was held in April at the DEA's Los Angeles office, and over 100 board licensees in the Los Angeles area attended. Evaluations from those who attended were strongly positive.

A copy of the draft agenda and the evaluations from the April meeting are provided in **Attachment 2.** A final agenda will be shared with the board at the October meeting.

The Board awarded 5 hours of CE credit for those pharmacists and pharmacy technicians who attended the April meeting.

This matter has been brought to the board to affirm that it will award 5 hours of CE credit for attendance at this November meeting.

c. FOR INFORMATION: Selection of Enforcement Committee Meeting Dates for 2012

During 2012, the Enforcement Committee will address implementation issues surrounding California's e-pedigree law, as well as other enforcement matters. As such, the meetings will be approximately six hours in length, with a lunch break.

Here are the proposed meeting dates for 2012. They are all Tuesdays, and are placed between board meetings and away from major holidays.

December 6, 2011 – Sacramento

March 13, 2012

June 12, 2012

September 11, 2012

December 4, 2012

d. FOR INFORMATION: Review of Enforcement Statistics and Performance of the Board

Attachment 3

The board's enforcement statistics are provided in **Attachment 3**. The performance statistics compiled by the DCA are not yet available for the first quarter, so attached is the fiscal year 2010-11 report.

e. FOR INFORMATION: First Quarterly Update of the Committee's Strategic Performance Goals 2011/12.

Attachment 4

Attachment 4 contains the first quarter's update report on the committee's strategic plan.

Attachment 1

1707.5. Patient-Centered Labels for Prescription Drug Containers; Requirements

(a) Labels on drug containers dispensed to patients in California shall conform to the following format:

(1) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 10-point sans serif typeface or, if requested by the consumer, at least a 12-pooint typeface, and listed in the following order:

(A) Name of the patient

(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name of the drug, or the generic name and the name of the manufacturer.

(C) The directions for the use of the drug.

(D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

(2) For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1).

(3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface.

(4) When applicable, directions for use shall use one of the following phrases:

(A) Take 1 [insert appropriate dosage form] at bedtime

(B) Take 2 [insert appropriate dosage form] at bedtime

(C) Take 3 [insert appropriate dosage form] at bedtime

(D) Take 1 [insert appropriate dosage form] in the morning

(E) Take 2 [insert appropriate dosage form] in the morning

(F) Take 3 [insert appropriate dosage form] in the morning

(G) Take 1 [insert appropriate dosage form] in the morning, and Take 1 [insert appropriate dosage form] at bedtime

(H) Take 2 [insert appropriate dosage form] in the morning, and Take 2 [insert appropriate dosage form] at bedtime

(I) Take 3 [insert appropriate dosage form] in the morning, and Take 3 [insert appropriate dosage form] at bedtime

(J) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, and 1 [insert appropriate dosage form] in the evening

(K) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, and 2 [insert appropriate dosage form] in the evening

(L) Take 3 [insert appropriate dosage form] in the morning, 3 insert appropriate dosage form] at noon, and 3 [insert appropriate dosage form] in the evening

(M) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, 1 [insert appropriate dosage form] in the evening, and 1 [insert appropriate dosage form] at bedtime

(N) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, 2 [insert appropriate dosage form] in the evening, and 2 [insert appropriate dosage form] at bedtime

(O) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, 3 [insert appropriate dosage form] in the evening, and 3 [insert appropriate dosage form] at bedtime
(P) If you have pain, take __ [insert appropriate dosage form] at a time. Wait at least __ hours before taking again. Do not take more than __ [appropriate dosage form] in one day
(b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.
(c) Beginning in October 2011the board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.
(d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services in the patient's language. If interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.
(e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.
(f) As used in this section, "appropriate dosage form" includes pill, caplet, capsule or tablet.

Authority cited: Sections 4005 and 4076.5, Business and Professions Code. Reference: Sections 4005, 4076, and 4076.5, Business and Professions Code.

Attachment 2

DRAFT

DRUG ENFORCEMENT ADMINISTRATION

Diversion of Controlled Substances
What every pharmacist should know to prevent diversion

Sponsored by
DEA Los Angeles Field Division
and
California State Board of Pharmacy
November 7, 2011

Location:
Loma Linda University
School of Pharmacy

DRAFT AGENDA

November 7, 2011

9:30 am	Welcome/Orientation *DEA Senior Manager* *California Board of Pharmacy Executive Officer Virginia Herold* *DEA Diversion Program Manager Mike Lewis*
10:00 am	Drug Trafficking /Trends in Los Angeles *DEA Diversion Program Manager Mike Lewis*
11:00 am	Break
11:15 am	Controlled Substances Utilization Review and Evaluation System -- CURES Records, Inquiries and Reports *CURES staff*
12:30 pm	Lunch
1:30pm	Pharmaceutical Supply Chain Thefts Reporting and Prevention *Judi Nurse*
2:00 pm	Corresponding Responsibility *Virginia Herold/Mike Lewis/Judi Nurse/Marlon Whitfield*
2:30 pm	Break
3:00 pm	Board actions against Internet Prescribing *Virginia Herold*
3:15 pm	Questions to Panel *D/I's, Board Investigators*
4:00 pm	Adjournment

EVALUATION RESULTS - April 12, 2011 presentation

Diversion of Controlled Substances - What Every Pharmacist Should Know to Prevent Diversion

(71 participants responded)

	1 needs work	2	3 satisfactory	4	5 great
Overall Conference		1	11	25	35
Topics Timely and Relevant			10	23	39
Facility	2	5	19	22	24
Quality of Speakers		2	12	20	39
(totals)	2	8	52	90	137

Specific comments:

Very informative. The changes that have impacted pharmacy in terms of threats over the past 10 years. Good content from DEA - thanks for the statistics. BOP stats backed up DEA stats nicely. CURES - did not seem any progress since the presentation of 2 years ago. Very good session and well worth the time.

Medical Board and the LA AG's Office should have participated. We have to have a better system of identifying and sanctioning errant prescribers (DEA - MED Board).

I liked the presentation regarding the different fraud schemes and how pharmacies should enforce strict internal controls.

Participant name badges. Pre-test / post-test. Longer question session. More comments from Lee Worth!

Would be helpful to have print-out of powerpoint. More time for questions.

Very good presentation.

Have pre-access to the powerpoint presentation. Have more educational seminars in Southern CA. Create educational program for high school. DEA needs to be in front screen for educational purpose.

Overall presentation was very informative.

Need larger space. Very informative on a timely topic. Would like to see more workshops provided.

Excellent content, a lot of useful info. Transcripts of presentations would be helpful.

Informative. Live performance gave "stories" to provide practical examples of what types of abuse and diversions are occuring currently and what type of people that have history of these abuses. Up-to-date info.

Would like more info for County Public Health Depts that store mass quantities of meds for emergencies.

Very good information. Would be good to hear early on in practice. I know when I first started working, I was definitely naïve to this and I filled a fake Rx. We did catch him though because he came back and said I didn't fill enough. Would have liked better explanation of CURES - speakers not quite as good.

Conference room is too small to accommodate all participants. Long line to get into the building.

Would like more programs if possible in Orange County.

Everything was good. We need more classes like this. I still need 15 more continued education credits for my pharmacy technician certification.

Room hot - poor ventilation. Very uncomfortable.

Offer program to all local CPhA chapters. Please post DEA and BOP slide sets on BOP web page.

The breaks were too long. Too much to cover - cut breaks much shorter. Very enjoyable, need more publicity. I only accidently heard about the program.

Promote moral standard of pharmacist fulfilling - corresponding responsibility of dispensing controlled drugs.

Need handouts. Could have used this 5 years ago!

Did not like the location where CE conference was held. Like the topic and its application.

Perhaps topic on consequences of diversion of drugs (sanctions / criminal convictions).

Room not conducive - hard to see slides due to setup. Too cold in morning. Would have been nice to have handouts -- are we able to get those slides? When people have questions -- presenter should "repeat" the question.

Use different color on your powerpoint presentation. It is hard to see red print on a purple background. Thank you so much for all the info. Please have more of these sessions.

Fire escapes -- LOCKED EMERGENCY ONLY? No way to walk stairs. How to escape 2nd floor? Excellent presentation.

Great workshop - very informative. Hope to see more meetings like this one. Next topic: please include e-Rx on controlled substances.

Suggest a larger conference room. Also suggest a different location - some hospitals will donate the use of their conference room free, or low cost parking. Overall, program speakers were very good.

Slides by Judi Nurse and Valerie Sakamura: print on powerpoint slides too small. Red font on dark blue background makes it hard to read as there is reduced contrast. Recommend yellow font instead of red font. Misspellings on powerpoint slides need correcting.

Red highlighting on Judi Nurse presentation is unreadable in back of room. Get bigger room next time. Have Judi use microphone. Have all presenters sit 50' from screen and make sure they can read slides. Thanks.

Room too small for turnout. Hard to read Judi's slides. Location not too convenient.

Would be helpful to have powerpoint slides printed out. Please do use the microphones. The powerpoint slides were too cluttered, print too small to read, color of font against background too hard to read. Some speakers offered practical suggestions/applications for RPh - that was helpful.

CURES section was not as informative as the other lectures. Best section was the one discussing how pharmacies and pharmacists deal with diversion. Internet pharmacy presentation - informative.

Very enjoyable. I wish there was time for networking.

Great topics. Judy did a good job.

Was hard to hear some speakers and see powerpoint. Cold too.

Good to help educate everyone of the magnitude of the problem.

Judi Nurse: learn to use microphone. PowerPoint suggestions: Do not use blue background. Do not use red letters. Black letters and white background make easier to see. Do not use small font. Our eyes are old and need bigger letters to see.

Perhaps a syllabus of the program. To save paper, you could have it on the website for download. It's too much information to write down and a lot of the points were not touched upon by the speakers. I'm glad the CURES reps were there, however, they weren't around in the afternoon.

Handouts for powerpoint presentations would be good or at least a website where we can print them out prior to or after the program. Don't use red letters on blue slide - hard to read; maybe you can underline instead. Otherwise a great presentation.

Need to have speakers using microphone. Slides are hard to read. Have copies of slides as handouts.

I liked Michael Lewis' presentation. It was very interesting and eye-opening. I did not like the CURES presentation. It was very choppy and it didn't flow well.

A very interesting and necessary presentation. Please keep updating material and having these presentations! More about what the DEA is looking for. What are things that are an issue? What should pharmacies be documenting?

Would like a copy of slides printed out to take back to work and discuss with my associates. Like to have a listing of who to call with specific questions or problems. Procedure to follow if you are presented with a "group" of people that you believe to be attempting to procure medications by questionable means (diversion).

Like hearing of responsibility of RPhs. Contact info / who to call for questions. Opportunities for improvement: Quality of sound / difficult to identify addiction and responsibility of RPh. Referrals to health insurance / PBM if fraud/abuse suspected. P.S. I'd be happy to speak! I work for Aetna F/A Unit.

Can you also include situations in long-term care facilities and board-n-care and intermediate care facilities? I work for a pharmacy catering to ICF patients who are under the care of an LVN and the LVN or RN are ordering refills of their meds. For controlled drugs III-V refills are called in by LVN of the ICF, not MD's office - is this a violation of the board?

Recommendations to make specific discussion regarding long-term care pharmacies and its regulations in details. More emphasis on "authorized" prescriber having different RNs/LVNs giving orders, either via phone or fax. Thank you!

Attachment 3

Department of Consumer Affairs

California State Board of Pharmacy

Performance Measures

Annual Report *(2010 – 2011 Fiscal Year)*

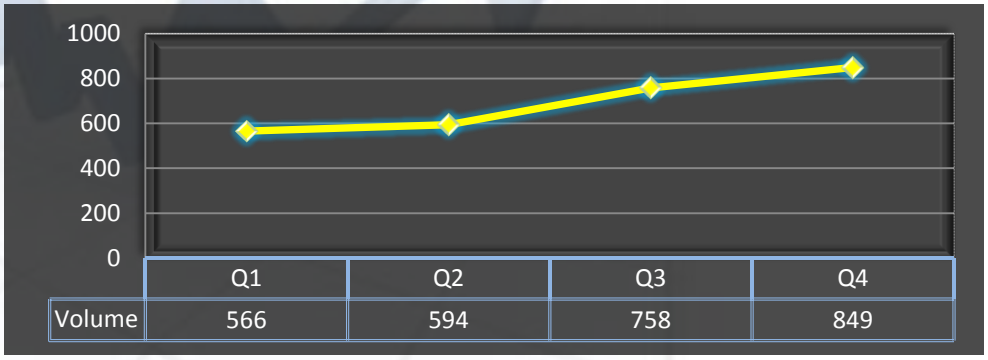
To ensure stakeholders can review the Board's progress in meeting its enforcement goals and targets, we have developed a transparent system of performance measurement. These measures are posted publicly on a quarterly basis.

This annual report represents the culmination of the first four quarters worth of data.

Volume

Number of complaints and convictions received.

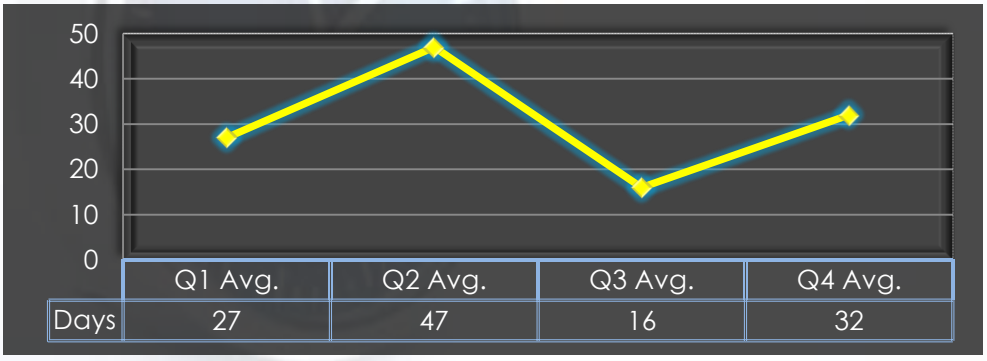
The Board had an annual total of 2,767 this fiscal year.



Intake

Average cycle time from complaint receipt, to the date the complaint was assigned to an investigator.

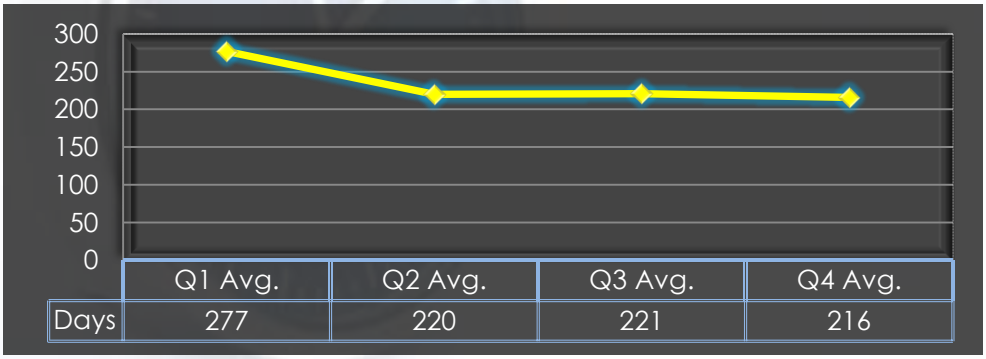
The Board has set a target of 20 days for this measure.



Intake & Investigation

Average cycle time from complaint receipt to closure of the investigation process. Does <u>not</u> include cases sent to the Attorney General or other forms of formal discipline.

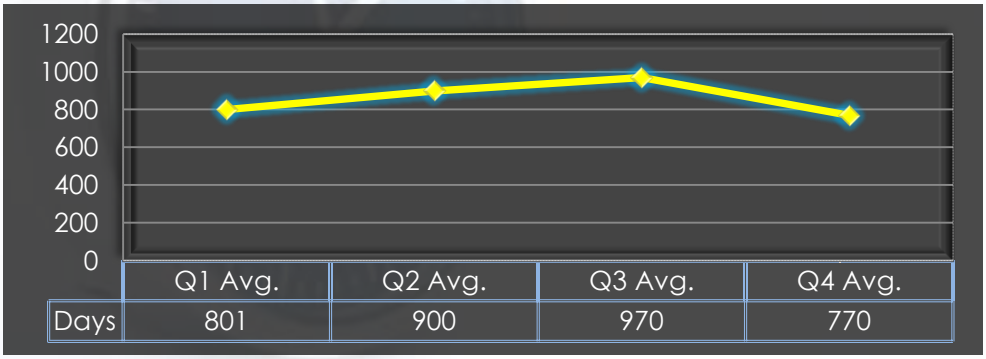
The Board has set a target of 210 days for this measure.



Formal Discipline

Average number of days to complete the entire enforcement process for cases resulting in formal discipline. (Includes intake and investigation by the Board, and prosecution by the AG)

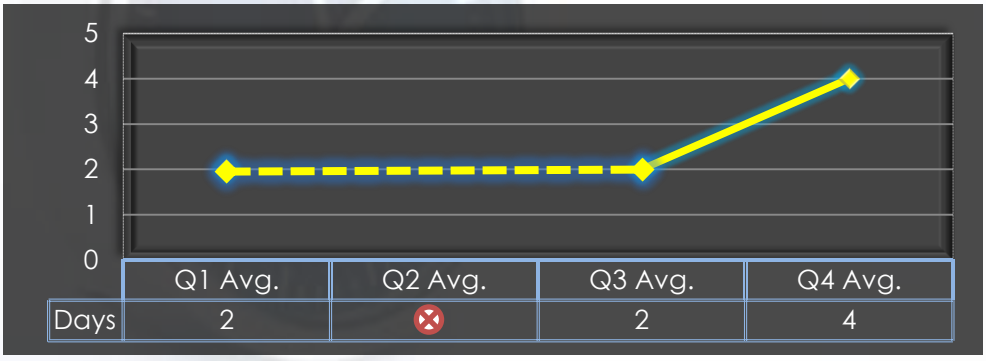
The Board has set a target of 540 days for this measure.



Probation Intake

Average number of days from monitor assignment, to the date the monitor makes first contact with the probationer.

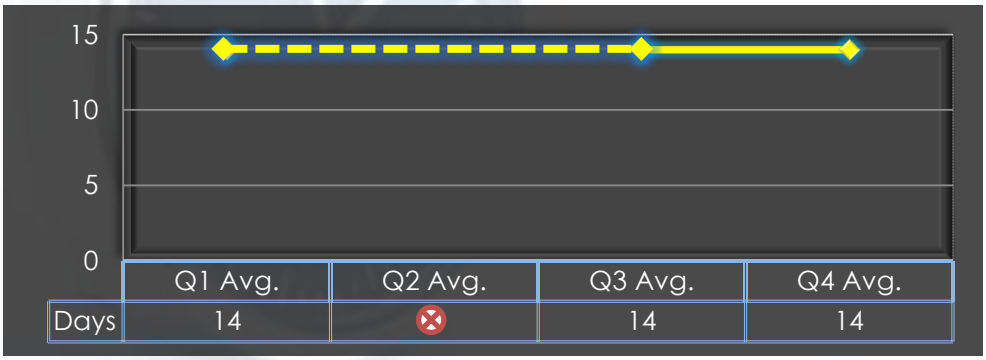
The Board has set a target of 30 days for this measure.



Probation Violation Response

Average number of days from the date a violation of probation is reported, to the date the assigned monitor initiates appropriate action.

The Board has set a target of 7 days for this measure.



Board of Pharmacy Enforcement Statistics
Fiscal Year 2011/2012

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 10/11
Complaints/Investigations					
Received	611				611
Closed	413				413
Pending (at the end of quarter)	1772				1772
Cases Assigned & Pending (by Team) at end of quarter*					
Compliance Team	537				537
Drug Diversion/Fraud	226				226
Probation/PRP	101				101
Routine Inspection	33				33
Mediation/Enforcement	64				64
Criminal Conviction	561				561
Application Investigations					
Received	217				217
Closed					
Approved	135				135
Denied	18				18
Total**	243				243
Pending (at the end of quarter)	209				209
Letter of Admonishment (LOA) / Citation & Fine					
LOAs Issued	20				20
Citations Issued	239				239
Citations Closed	273				273
Total Fines Collected***	$319,115.00				$319,115.00

* This figure include reports submitted to the supervisor.

** This figure includes withdrawn applications.

*** Fines collected (through 9/30/2011 and reports in previous fiscal year.)

Board of Pharmacy Enforcement Statistics
Fiscal Year 2011/2012

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 10/11
Administrative Cases (by effective date of decision)					
Referred to AG's Office*	85				85
Pleadings Filed	61				61
Pending					
Pre-accusation	194				194
Post Accusation	279				279
Total*	533				533
Closed					
Revocation					
Pharmacist	2				2
Intern Pharmacist	0				0
Pharmacy Technician	16				16
Designated Representative	1				1
Pharmacy	0				0
Revocation,stayed; suspension/probation					
Pharmacist	2				2
Intern Pharmacist	0				0
Pharmacy Technician	1				1
Designated Representative	0				0
Pharmacy	0				0
Revocation,stayed; probation					
Pharmacist	3				3
Intern Pharmacist	0				0
Pharmacy Technician	6				6
Designated Representative	0				0
Pharmacy	3				3
Surrender/Voluntary Surrender					
Pharmacist	0				0
Intern Pharmacist	0				0
Pharmacy Technician	7				7
Designated Representative	0				0
Pharmacy	0				0

Board of Pharmacy Enforcement Statistics
Fiscal Year 2011/2012

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 10/11
Public Reproval/Reprimand					
Pharmacist	0				0
Intern Pharmacist	0				0
Pharmacy Technician	0				0
Designated Representative	0				0
Pharmacy	0				0
Cost Recovery Requested**	$88,205.00				$88,205.00
Cost Recovery Collected**	$78,117.99				$78,117.99

* This figure includes Citation Appeals

** This figure includes administrative penalties

Probation Statistics

Licenses on Probation					
Pharmacist	111				111
Intern Pharmacist	5				5
Pharmacy Technician	31				31
Designated Representative	2				2
Pharmacy	18				18
Wholesaler	2				2
Probation Office Conferences	17				17
Probation Site Inspections	73				73
Probationers Referred to AG for non-compliance	0				0

As part of probation monitoring, the board requires licensees to appear before the supervising inspector at probation office conferences. These conferences are used as 1) an orientation to probation and the specific requirements of probation at the onset, 2) to address areas of non-compliance when other efforts such as letters have failed, and 3) when a licensee is scheduled to end probation.

As of September 30, 2011

Attachment 4

GOALS, OUTCOMES, OBJECTIVES, AND MEASURES

ENFORCEMENT COMMITTEE

Goal 1: Exercise oversight on all pharmacy activities.

Outcome: Improve consumer protection.

Objective 1.1 Achieve 100 percent closure on all cases within 6 months.

Measure: Percentage of cases closed.

Tasks:

1. Complete all desk investigations within 90 days (for cases closed during quarter).

	N	< 90 days	< 120 days	< 180 days	Longer	Average Days
Qtr 1	383	135	51	91	106	164
		35%	13%	24%	28%	
Qtr 2						
Qtr 3						
Qtr 4						

2. Complete all field investigations within 120 days (for cases closed during quarter).

	N	< 120 days	< 180 days	< 270 days	Longer	Average Days
Qtr 1	275	123	50	37	65	187
		45%	18%	13%	24%	
Qtr 2						
Qtr 3						
Qtr 4						

Data is calculated from date received to the date the report was accepted by SI/Manager. Does not include split cases.

3. Close (e.g., no violation, issue citation and fine, refer to the AG's Office) all board investigations and mediations within 180 days.

Qtr 1	N	< 180	< 270	< 365	> 365
Closed investigations, no additional action, license approvals	298	242	25	14	17
Closed 4301 letters, license denials, withdrawn by Board	138	112	12	6	8
Cite and/or fine letter of admonishment	138	62	22	12	42
Attorney General's Office	84	34	29	6	15
Qtr 2	**N**	**< 180**	**< 270**	**< 365**	**> 365**
Closed investigations, no additional action, license approvals					
Closed 4301 letters, license denials, withdrawn by Board					
Cite and/or fine letter of admonishment					
Attorney General's Office					
Qtr 3	**N**	**< 180**	**< 270**	**< 365**	**> 365**
Closed investigations, no additional action, license approvals					
Closed 4301 letters, license denials, withdrawn by Board					
Cite and/or fine letter of admonishment					
Attorney General's Office					
Qtr 4	**N**	**< 180**	**< 270**	**< 365**	**> 365**
Closed investigations, no additional action, license approvals					
Closed 4301 letters, license denials, withdrawn by Board					
Cite and/or fine letter of admonishment					
Attorney General's Office					

Data is calculated from date received to date closed or referred to the AG.
One case may have multiple respondents. The actual number of citations and letters of admonishment issued are shown on the next page.

Objective 1.2	Manage enforcement activities for achievement of performance expectations.
Measure:	Percentage compliance with program requirements.
Tasks:	1. Administer the Pharmacists Recovery Program.

	Voluntary Participants	Participants Mandated Into Program	Noncompliant, Terminated From Program	Successfully Completed Program
Qtr 1				
Qtr 2				
Qtr 3				
Qtr 4				

2. Administer the Probation Monitoring Program.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Individuals	151			
Sites	20			
Tolled	28			
Inspections Conducted	67			
Successfully Completed	4			
Petitions to Revoke Filed	3			

3. Issue all citations and fines within 30 days.

	N	30 days	60 days	90 days	> 90 days	Average Days
Qtr 1	241	141	90	9	1	31
		59%	37%	4%	.4%	
Qtr 2						
Qtr 3						
Qtr 4						

4. Issue letters of admonishment within 30 days.

	N	30 days	60 days	90 days	> 90 days	Average Days
Qtr 1	15	10	5	0	0	25
		67%	33%	0%	0%	
Qtr 2						
Qtr 3						
Qtr 4						

These data are actual number of citations and letters of admonishment (LOA) issued.
One investigation may have multiple licensees that are issued a citation or LOA (split cases).

5. Obtain immediate public protection sanctions for egregious violations.

	Interim Suspension Orders	Automatic Suspension Based on Conviction	Penal Code 23 Restriction
Qtr 1	2	0	0
Qtr 2			
Qtr 3			
Qtr 4			

6. Submit petitions to revoke probation within 30 days once noncompliance with terms of probation is substantiated.

	30 days	60 days	> 60 days	N
Qtr 1	0	0	0	0
Qtr 2				
Qtr 3				
Qtr 4				

Objective 1.3	Achieve 100 percent closure on all administrative cases within 1 year.
Measure:	Percentage of administrative cases closed within 1 year.
Tasks:	1. File pleadings within 90 days of referral.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Number of Cases Referred to Attorney General's Office	77			
Accusations Filed	48			
Statement of Issues Filed	10			
Petitions to Revoke Probation Filed	3			

2. Percentage of administrative cases closed within 1 year.

	N	1 Year	1.5 Year	2 Year	2.5 Year	>2.5 Years	Average
Qtr 1	41	16	12	11	2	0	430
		39%	29%	27%	5%	0%	
Qtr 2							
Qtr 3							
Qtr 4							

Objective 1.4	Inspect 100 percent of all facilities once every 3 year inspection cycle ending 6/30/14.
Measure:	Percentage of licensed facilities inspected once every 3 year cycle.
Tasks:	1. Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public.

	Number of Inspections	Aggregate Inspections This Cycle	Percent Complete
Qtr 1	449	449	5%
Qtr 2			
Qtr 3			
Qtr 4			

2. Inspect sterile compounding pharmacies initially before licensure and annually before renewal.

	Number of Inspections	Number Inspected Late
Qtr 1	81	0
Qtr 2		
Qtr 3		
Qtr 4		

3. Initiate investigations based upon violations discovered during routine inspections.

	Number of Inspections	Number of Investigations Opened	Percent Opened
Qtr 1	530	60	11%
Qtr 2			
Qtr 3			
Qtr 4			

Objective 1.5	Initiate policy review of 25 emerging enforcement issues by June 30, 2011.
Measure:	The number of issues.
Tasks:	1. Monitor the implementation of e-pedigree on all prescription medications sold in California. *Oct. 2009:* *Executive Officer provides information about California's e-pedigree requirements at a SecurePharma Conference of drug manufacturers and wholesalers in Philadelphia and at a SpecialtyPharma Conference (contract drug manufacturers) in Phoenix.* *Dec. 2009:* *Executive Officer provides information about California's e-pedigree requirements at the Health Care Distributors Association Trace and Track Conference in Washington D.C.* *March 2010:* *Executive Officer provides information about California's e-pedigree requirements via a Webinar hosted by IBS.* *April 2010:* *Board reviews Food and Drug Administration guidance on a unique serialized identifier released March 26.* *Oct. 2010:* *Executive Officer provides information about California's requirements to a GS1 training session in San Francisco.* *Feb. 2010:* *Executive Officer provides presentation on California's e-pedigree requirements at FDA workshop on developing a track and trace.* 2. Implement federal restrictions on ephedrine, pseudoephedrine or phenylpropanolamine products. *Sep. 2006:* *Final phase-in of federal requirements takes effect on September 30. Board newsletter provides information for licensees.* *Oct. 2006:* *Board adds Consumer friendly materials regarding sales of these drugs to its website.* 3. Monitor the efforts of the Drug Enforcement Administration and Department of Health and Human Services to implement e-prescribing for controlled substances. *Nov. 2006:* *Board submits letter supporting change in Drug Enforcement Administration policy allowing prescribers to write multiple prescriptions for Schedule II drugs with "Do not fill before (date)" at one time, eliminating the need for patients to revisit prescribers merely to obtain prescriptions.* *Sep. 2008:* *Board submits comments on Drug Enforcement Administration proposed requirements for e-prescribing of controlled substances.* *Dec. 2009:* *Executive Officer meets with DEA officials in Washington D.C. to discuss interest in e-prescribing of controlled drugs.* *April 2010:* *Board reviews proposed Drug Enforcement Administration requirements for electronic prescribing of controlled substances.* *June 2010:* *Enforcement Committee received updates on DEA rule change.* *Jan. 2011:* *Board prepares guidance document for pharmacies and prescribers.* *May 2011:* *Medical Board reviews guidance document prepared to approve portion for prescribers.*

4. Evaluate establishment of an ethics course as an enforcement option.

Oct. 2008: *Board holds regulation hearing on proposed requirements for the ethics class.*

Jan. 2009: *Board adopts regulation.*

Sept. 2009: *Regulation takes effect.*

3rd Qtr 09-10: *Board subcommittee of two board members begins work with staff on suggested specific components and topics for the program, in compliance with board regulations.*

Oct. 2010: *First course provided.*

March 2011: *Second provider begins offering course.*

5. Participate in emerging issues at the national level affecting the health of Californians regarding their prescription medicine.

Dec. 2009: *Executive Officer provides presentation on California's e-pedigree requirements to three national association meetings.*

3rd Qtr 09-10: *Board initiates rulemaking on a regulation to establish requirements for patient-centered prescription container labels (see report on Legislation and Regulation Committee's Goals, Outcomes, Objectives and Measures).*

March 2011: *Executive Officer participates in PEW Trust's public forum on what was learned about the 2008 heparin adulteration.*

April 2011: *DEA and board cohost day-long conference for pharmacies of controlled substances. Due to interest and success, more conferences planned.*

6. Provide information about legal requirements involving e-prescribing to support the Governor's Health Care Initiative and its promotion of e-prescribing.

Sep. 2007: *Provided comments on proposed statutory requirements.*

Dec 2007: *Sought Department of Consumer Affairs' support for involvement in e-prescribing by the Administration.*

Provided comments on proposed e-prescribing initiatives.

Oct. 2008: *Executive Officer Herold joins a task force to achieve e-prescribing coordinated by the California HealthCare Foundation.*

Nov. 2008: *Board hosts conference on e-prescribing as part of department's professionals*

Achieving Consumer Trust Summit. The Medical Board and Dental Board join us as sponsors.

Jan. 2009: *Executive Officer Herold works with California HealthCare Foundation and Medical Board to plan joint activities with licensees to facilitate e-prescribing.*

March 2009: *Pharmacists and physicians in Visalia attend first of California HealthCare Foundation's public forums on e-prescribing.*

April 2010: *Board reviews Drug Enforcement Agency proposed regulations on e-prescribing of controlled substance.*

Nov. 2010: *Executive Officer provides presentations at annual California e-prescribing meeting.*

Jan. 2011: *Board prepares guidance document for pharmacies on DEA's requirements.*

May 2011: *Medical Board reviews same guidance document for prescribers.*

7. Implement in California the Center for Medicare and Medicaid Service requirements for security prescription forms that will be required in only four months for all written Medicaid and Medicare prescriptions.

Oct. 2008: *Requirements for security forms in place..*

2nd Qtr 09/10: *Board executive staff and several board members attend California Healthcare Foundation's annual summit to implement e-prescribing.*

8. Liaison with other state and federal agencies to achieve consumer protection.

1st Qtr 07/08: *Bimonthly meetings initiated with Department of Health Care Services audit staff to investigate pharmacies and pharmacists involved in MediCal fraud and drug diversion. Several joint investigations underway with state and federal agencies.*

2nd Qtr 07/08: *Bimonthly meeting with the Department of Health Care Services continue. Board inspectors attend 3-day-training with federal and state regulations on items involving fraud provided by the Office of Inspector General of the Department of Health and Human Services.*
Joint investigations with other state and federal agencies continue that involve the board's jurisdiction.

3rd Qtr 07/08: *Bimonthly meetings with the Department of Health Care Services continue. Board works with the Drug Enforcement Administration on joint investigations and receives specialized training.*

4th Qtr 07/08: *Board staff meets with staff of the California Department of Public Health regarding joint inspections of licensed healthcare facilities in California to identify and remove recalled drugs.*

3rd Qtr 08/09: *Executive staff meet with Department of Health Care Services investigators on cases of mutual concern. Board investigators work with federal and state drug enforcement officers on search warrants and mutual investigations.*

4th Qtr 08/09: *Board staff meets with staff of the California Department of Public Health regarding joint inspections of licensed healthcare facilities in California to identify and remove recalled drugs.*
Executive staff meet with Department of Health Care Services investigators on cases of mutual concern. Board investigators work with federal and state drug enforcement officers on search warrants and mutual investigations.
The federal Drug Enforcement Administration provides training to board staff on new requirements for online pharmacies selling controlled substances.

2nd Qtr 09/10: *Executive staff meet with Department of Health Care Services staff on mutual investigations; DEA staff in Washington D.C. on enforcement issues involving controlled drugs; the U.S. Attorney General's office in Sacramento on two major enforcement matters; and worked with the Licensing and Certification and Food and Drug Branch of the California Department of Public Health on issues of mutual concern.*

3rd Qtr 09/10: *Board supervising inspectors work with federal, state and local law enforcement agencies on emerging enforcement issues and investigations, and worked with the Licensing and Certification and Food and Drug Branch of the California Department of Public Health on issues of mutual concern.*
Board staff redirected to complete HIPDB reporting.

4th Qtr 09/10: *Board staff continue to report to HIPDB.*

2nd Qtr 10/11: *Board supervising inspectors work with federal, state and local law enforcement agencies on emerging enforcement issues and investigations, and worked with the Licensing and Certification and Food and Drug Branch of the California Department of Public Health on issues of mutual concern.*

3rd Qtr 10/11: *Board supervising inspectors work with federal, state and local law enforcement agencies on emerging enforcement issues and investigations, and worked with the Licensing and Certification and Food and Drug Branch of the California Department of Public Health on issues of mutual concern. Executive staff attend joint meeting with California District Attorneys Association.*

9. Work with the California Integrated Waste Management Board to implement requirements for model programs to take back unwanted prescription medicine from the public.

March 2008: *Second meeting with state agency stakeholders on developing components for model programs that conform with diverse state agency security and safety requirements.*

June 2008: *Supervising pharmacist inspector attended a two-day multi-disciplinary conference hosted by the Integrated Waste Management Board on drug take-back programs.*

Aug. 2008: *Executive Officer Herold speaks at conferences sponsored by the California Integrated Waste Management Board.*

Oct. 2008: *Enforcement Committee hears presentations on drug take-back programs, medical waste management processes and the take-back of sharps. Board to submit comments to California Integrated Waste Management Board on model programs for take-back programs.*

Nov. 2008: *Executive Officer provides written and verbal testimony at California Integrated Waste Management Board hearing on the model guidelines.*

Dec. 2008: *Executive Officer participates in public hearing at the California Integrated Waste Management Board on possible changes to the model guidelines adopted by the California Integrated Waste Management Board in November.*

Feb. 2009: *California Integrated Waste Management Board amends model guidelines to include provisions advanced by the board.*

Jan. 2010: *Board writes article on the guidelines for publication in the next issue of The Script. Board executive staff attend meetings on "take back drugs" at a statewide conference of the California Integrated Waste Management Board. Executive Officer provides presentation on the CIWMB Model Guidelines at a meeting of 20 rural California counties.*

March 2010: *Board publishes the guidelines in The Script.*

April 2010: *Board inspector will collect information about take back programs in California pharmacies during inspections.*

Aug. 2010: *Executive Officer provides information regarding board policy on drug take back programs in pharmacies to CalRecycle and its draft report on model take back programs. Written comments are later provided on behalf of the board.*

Jan. 2011: *Board reviews final version of CalRecycle's report.*

May 2011: *Final report released.*

10. Inspect California hospitals to ensure recalled heparin has been removed from patient care areas.

4th Qtr 07/08:	*Board initiates inspections of 40 California hospitals looking for counterfeit heparin and unlicensed sales but discovers recalled heparin still in 40 percent of hospitals inspected. Board notifies the Food and Drug Administration and California Department of Public Health and initiates inspections of 533 hospitals during April-June.* *Recalled heparin is found in 94 of these facilities. Data reported to board during June Board Meeting.*
1st Qtr 08/09:	*The Script highlights problems found in heparin inspections. Citations and fines issued to facilities with recalled heparin. Work with hospitals begins to strengthen drug control within facilities.*
2nd Qtr 08/09:	*Hospitals and Pharmacists-in-Charge fined where recalled heparin was discovered by the board.*
3rd Qtr 08/09:	*First stakeholder meeting scheduled to discuss drug distribution within hospitals.*
March 2009:	*First stakeholder meeting convened.*
June 2009:	*Second stake holder meeting convened. Development of model guidelines for recalls underway.*
Sep. 2009:	*Stakeholder meeting convened.* *Recall guidelines evaluated and additional comments solicited.*
Jan. 2010:	*Board reviews final version of recommended steps for addressing recalls in hospitals.*
April 2010:	*Manuscript of addressing recalls in hospitals completed, compiled into finished report and posted on Website.* *Executive officer works with the Healthcare Distributors Management Association (representing drug wholesalers) to secure notices of recalls more timely to share with board subscriber list.* *Appeals of citations and fines nearly complete.*
May 2010:	*Outstanding enforcement/compliance completed.*
2011:	*Board receives copies of drug recalls at the pharmacy level and releases them through the subscriber alert system.*
March 2011:	*Board participates in international conference convened by the PEW Trust on the 2008 heparin contamination to identify ways to prevent a reoccurrence.*

11. Promulgate regulations required by SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008) for recovery programs administered by Department of Consumer Affairs health care boards.

4th Qtr 08/09: *Draft proposals for required components 1-6 developed.*

1st Qtr 09/10: *Draft proposals for required components 7-13 developed.*

3rd Qtr 09/10: *Board hears presentation on uniform standards. Staff/counsel identifies changes required to implement standards.*

1st/2nd Qtr 10/11: *Proposed changes to Board Disciplinary Guidelines drafted. Staff continue working with DCA on standards.*

2nd Qtr 10/11: *Board staff begin incorporating standards for Board consideration.*

3rd Qtr 10/11: *Changes to standards are approved by Substance Abuse Coordination Committee.*

4th Qtr 10/11: *Board updated on progress of language development and incorporated into disciplinary guidelines for Board consideration.*
Board staff initiate review of reporting requirements.

12. Develop and release Request for Proposal for vendor for Department of Consumer Affairs health care boards that operate license recovery programs.

4th Qtr 08/09: *Provisions for Request for Proposal developed: Request for Proposal released.*

2nd Qtr 09/10: *Contract awarded.*

13. Participate in Department of Consumer Affairs Consumer Protection Enforcement Initiative to strengthen board enforcement activities and reduce case investigation completion times for formal discipline.

1st/2nd Qtr 09/10: *Work with Department of Consumer Affairs on identification of Enforcement Best Practices.*
Board discusses SB 1441 components for Diversion Programs to strengthen consumer protection enforcement staff attend Enforcement Best Practices work group.

3rd Qtr 09/10: *Board senior staff and Board President meet with Department of Consumer Affairs to discuss enforcement program enhancements in SB 1111.*
Board staff begin submitting monthly reports detailing workload and improvement efforts to the department.

4th Qtr 09/10: *Board hears presentation on CPEI and current status of department and board efforts.*

1st/2nd Qtr 10/11: ***Board sponsors legislation to secure records more timely from licensees.***
Board conducts civil service exams for inspector and supervising inspector classifications. Hiring freeze prevents hiring of staff.

2nd Qtr 10/11: *Board submits freeze exemptions, all are denied.*

3rd Qtr 10/11: *Governor Brown established a formal hiring freeze.*
New hiring freeze exemptions prepared for eight inspector positions.

4th Qtr 10/11: *Board staff secure an exemption to hire eight inspectors.*

14. Initiate criminal conviction unit to review and investigate rap sheets received on licenses for arrests or convictions.

1st Qtr 09/10: *Unit created via budget change proposal, 6.5 staff hired, trained, initiate work.*
There are 1,287 rapsheet investigations under review.

2nd Qtr 09/10: *There are 1,037 rapsheet investigations under review.*

3rd Qtr 09/10: *There are 652 rapsheet investigations under review.*

4th Qtr 09/10: *Post implementation review of Criminal Conviction Unit completed. Enforcement Committee advised of new unit outcomes.*

4th Qtr 10/11: *Board staff secure a second exemption to hire three additional inspectors. Six new staff begin. Training is limited because of travel restrictions.*

15. Complete comprehensive review of investigative and enforcement internal processing to identify process improvements.

1st Qtr 09/10: *Board staff implemented on-line assignment of investigations.*
Board staff implemented on-line review of draft pleadings.

2nd Qtr 09/10: *Board staff began drafting Default Decision and Orders.*

4th Qtr 09/10: *Board staff began drafting Petition to Revoke Probation Pleadings.*
Board staff implemented a pilot program to provide pre-populated investigation reports to the Compliance Team.

3rd Qtr 10/11: *Board staff review citation and fine program.*

4th Qtr 10/11: *Board staff evaluates complaints closed without findings to ensure integrity of the process. Some deficiencies noted. Process improvements identified and staff educated.*

16. Complete review of pharmacies dispensing prescriptions for Internet web site operators.

2010: *Updates on disciplinary actions provided at board meetings and in The Script.*

17. Provide updates on the board's reporting to the Healthcare Integrity and Protections Data Bank (HIPDB).

1st Qtr 10/11: *656 reports submitted (includes initial and revised submissions).*

2nd Qtr 10/11: *334 reports submitted (includes initial submissions).*

3rd Qtr 10/11: *432 reports submitted.*

4th Qtr 10/11: *96 reports submitted. Position vacant effective September 2011 due to employee retirement. Recruitment pending with Department of Consumer Affairs Human Resources.*